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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,463	01/10/2002	Davide R. Grassetti	107-000110US	9878

22798 7590 11/13/2008

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
11/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/044,463	GRASSETTI ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-16 and 20-24* is/are pending in the application.

4a) Of the above claim(s) *3,7-9,13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,10-12 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted July 25, 2008 is acknowledged.

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims are directed to a method comprising administer the disulfide compounds herein to an individual in need of immune response modulation. Examples of those individuals are given in the specification, paragraphs 0095-0102, e.g., immune compromised patients (0100), patients with Lentivirus infection (paragraph 0099) is one of the examples. The effective amounts are defined as about 10 μg to about 5 g per kg of body weight (0087).

2. Claims 1-2, 5-6, 10-12, and 20-24 rejected under 35 U.S.C. 102(b) as being anticipated by Grassetti (US 4,378,364, IDS), as evidenced by Barber et al. (US 5,662,896) and Tagawa. .

3. Grassetti teaches a method of lessening the pains and increasing the well-being of patients with carcinomas, including those undergo chemotherapy, an effective amount of 6,6'-dithiodinicotinic acid, wherein the preferred amounts is about 500 mg to about 900 mg per day. See, particularly, the examples, and the abstract and the claims. As to "modulating an immune response," or other limitations that further define the immune response (claims 10-12), recited in the preamble, it is noted that preamble is generally not accorded any patentable weight where it

merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

4. The added step in the claimed method: "identifying an individual in need of immune response modulation;" is inherently met by the method of treating cancer patient disclosed in the reference, as cancer patients are recognized as "in need of immune response modulation" See, the abstract in Tagawa and columns 1-2 in Barber et al.

5. Further, applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter anticipated by the prior art.

Response to the Arguments

Applicants' remarks submitted July 25, 2008 have been fully considered, but are not persuasive.

Applicants argue that the claimed invention is not anticipated because not all patients undergoing chemotherapy are in need of immunomodulation. The examiner respectfully disagrees, and maintains his position as stated in the prior office action:

6. "The fact that some of the cancer patients are treated without the employment of immunomodulation does not mean those patients are not immune compromised. All cancer patients are somewhat immune compromised and therefore would meet the limitation of "patient in need thereof" herein. *See, paragraph 0100 of the specification herein*. Further, Grassetti teaches a method of lessening the pains and *increasing the well-being* of patients with carcinomas, including those undergo chemotherapy. Those undergo chemotherapy and with pain are deemed to be immune compromised."

7. Paragraph 0100 of this application states:

"TFDs can also be used to boost immune response in immunocompromised individuals, e.g., patients undergoing chemotherapy or individuals with genetic defects of immune function or the elderly. Patients undergoing chemotherapy may have lower than normal numbers of immune cells and the immune cells which are present may have had their functional activity compromised by the chemotherapy. In this case, it is beneficial to administer one or more TFD(s) to patients who are undergoing or have had chemotherapy treatment to boost their immune cell populations and functions."

Therefore, treatment of patients undergoing chemotherapy would meet the limitation of "in need thereof".

Furthermore, practicing of Grassetti's method would have inevitably practiced the claimed method as a method for treatment in medicinal art is understood as a method of massive treatment of patients in need of the treatment, even the "in need thereof" is narrowly interpretated as 30% of patients undergoing chemotherapy.

Applicants also argue that the claims are directed to a new method, however, fails to identify the difference between the claimed invention and the "ultimate utilities" disclosed in the prior art, i.e., treatment of patients undergoing chemotherapy with TFDs. The cited reference

teaches the employment of the same compound for treatment of the same patients with the same amounts herein and clearly anticipated the claimed invention.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617